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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,388	02/05/2004	Horst Georg Zerbe	2004-0189	3058

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
08/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,388	ZERBE ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-31 and 33-56* is/are pending in the application.

4a) Of the above claim(s) *41-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-31,33-40 and 52-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed March 28, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Action is made Non-Final.

Claims

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 33 recites the limitation "the water-soluble polymer" in line two. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

Claims 24-29, 31, 33-36, 38-40 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554).

Majeti disclose films comprising one or more layers for the delivery of nicotine transmucosally. The compositions comprise polymers such as polyvinyl alcohol, hydroxypropyl cellulose, polyethylene oxide homopolymers, polyvinylpyrrolidone (PVP) and mixtures thereof. The polymers may comprise 40% to 90% of the composition (col. 4, line 55 to col. 5, line 5). Plasticizers are included such as polyethylene glycol and sorbitol (col. 5, lines 45-53) encompassing claims 31, 34 and 55 and may comprise from 2% to 10% encompassing claim 35. The adhesive layer' thickness ranges from 0.1 mm to 7 mm, encompassing claims 25 and 28. The concentration of nicotine varies from 1mg to 100mg (col. 4, lines 9-11) and comprises 1% and 2% of the Examples, encompassing 26, 27 and 38. Aromatic oils are included in the compositions and include menthol, encompassing claims 39, 40 and 56. Other ingredients include chlorhexidine, dispersants, surfactants, humectants, pigments and colorings.

The reference differs from the instant claims insofar as it does not disclose all the components in one composition.

A reference is analyzed using its broadest teachings. MPEP 2123 [R-5].

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Corning Glass Works v.

Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742.

Consistent with this reasoning, it would have been obvious to have selected various combinations of various disclosed ingredients from within a prior art disclosure, to arrive at compositions "yielding no more than one would expect from such an arrangement".

In regards to hydroxypropyl methylcellulose in claim 28, it has been disclosed in

the art to be use interchangeably or in mixtures with hydroxypropyl cellulose[1]. It is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant disclosure. It is also prima facie obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See MPEP 2144.07.

It would have been obvious to one of ordinary skill in the art to have used hydroxypropyl methyl cellulose in place of hydroxypropyl cellulose as a hydrophilic material in the compositions of the primary reference based on the prior art's recognition that such species are equivalent in function, as supported by cited precedent. It would also have been obvious to add tartaric acid to the compositions of the primary reference motivated by the desire to obtain its function as a flavoring (also see footnote below) used in oral films.

In regards to the film exhibiting instant wettability followed by rapid dissolution, the films of the reference are made of substantially the same water soluble polymers, such as PVP and hydroxy alkyl cellulose, in substantially the same amounts as the instant claims and therefore should have substantially the same properties. Furthermore it would take no more than routine optimization to one of skill in the art to determine the proportions of polymers to arrive at a film with the desired rate of water hydration and

[1] Acharya (US 5,686,094) discloses cellulose alkyl hydroxylates such as hydroxypropylmethyl cellulose, hydroxypropyl cellulose, hydroxymethyl cellulose and hydroxyethyl cellulose are used to control the release of an active agent and may be used in mixtures or alone. The reference also discloses tartaric acid as a flavoring.

dissolution. See MPEP 2144.05 II.

2) Claims 10-23 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554) as applied to claims 24-29, 31, 33-36, 38-40 and 53-56 in further view of Story et al. (US 4,944,949).

The primary reference, Majeti, is discussed above. The reference discloses surfactants may be incorporated into the compositions. The reference differs from the instant claims insofar as it does not disclose the compositions comprise a mixed surfactant system comprising polyoxyethylene sorbitan fatty acid ester or alpha-hydroxy-omega-hydroxypoly(oxyethylene)-poly(oxypropylene)poly(oxyethylene) block copolymer, and polyoxyethylene alkyl ether or a polyoxyethylene castor oil derivative.

Story et al. is used as a general teaching to disclose surfactants are used to dissolve drugs. Surfactants can be variously classified, and often by reference to the nature of the hydrophilic region, which can be anionic, cationic, zwitterionic or nonionic. The preferred surfactants of the reference are nonionic surfactants, which include polyoxyethylated surfactants, including polyoxyethylated glycol monoethers, polyoxyethylated fatty acids, polyoxyethylated sorbitan fatty esters, and polyoxyethylated castor oils. However, other nonionic surfactants are also particularly appropriate, including sorbitan fatty acid esters, poloxamers, polyethylene glycol fatty acid esters and polyethoxylated glyceryl fatty acid esters. Whatever the precise chemical structure of the surfactant or surfactants used, it is generally preferred to use one or more of those that have been already cleared for human ingestion. Therefore,

surfactants with a low toxicity are preferred. One factor affecting the choice of surfactant or surfactants to be used is the hydrophilic-lipophilic balance (HLB), which gives a numerical indication of the relative affinity of the surfactant for aqueous and non-aqueous systems. There may be cases where a mixture of two or more surfactants provides an improved degree of solubilization over either surfactant used alone. Additional components may be added to the compositions such as preservatives, sweeteners and flavoring agents.

The reference differs from the instant claims insofar as it does not disclose the oral compositions as a monolayer film or the oral compositions comprising water-soluble polymers.

It would have been obvious to one of ordinary skill in the art to have used the surfactants and mixtures thereof in the compositions of the primary reference motivated by the desire to ensure the desired pharmaceutical active agent was thoroughly dissolved and made a uniform mixture throughout the film as taught by the Story et al.

3) Claims 30 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Majeti (US 5,599,554) as applied to claims 24-29, 31, 33-36, 38-40 and 53-56 in further view of Stanley et al. (US 5,783,207).

The primary reference, Majeti, is discussed above. The reference differs from the instant claims insofar as it does not disclose the compositions comprise a nicotine slat such as nicotine salicylate.

Stanley et al. disclose dosage forms comprising nicotine and its salts.

Nicotine is released from a dosage form and absorbed through the intra-oral mucosal surfaces as the nicotine-containing matrix releases nicotine within the user's mouth. Nicotine is available in either the free base or salt form. Nicotine base is readily absorbed through mucosal membranes but is highly volatile. Nicotine salts, on the other hand, are not readily absorbable through mucosal membranes but are much more stable. Pharmaceutically acceptable nicotine salts include, but are not limited to nicotine hydrochloride and nicotine salicylate. In an alkaline environment, i.e., pH above about 7, and in the presence of an aqueous medium, such as saliva within the oral cavity, nicotine salts react to form nicotine base (col. 7, lines 38-60). In addition to nicotine in a releasable form, which is readily absorbed transmucosally; the nicotine-containing compositions in accord with the present invention may contain other ingredients such as flavorings, sweeteners, flavor enhancers, lubricants, binders and fillers.

The reference differs from the instant claims insofar as it does not disclose the matrices comprise polyvinyl pyrrolidone and hydroxypropyl methyl cellulose and rapidly disintegrate or soften immediately.

It would have been obvious to one of ordinary skill in the art to have used the nicotine salts and other ingredients in the compositions of the primary reference motivated by the desire to produce a stable dosage form that comprises a nicotine active ingredient that can form the nicotine base when introduced into the oral cavity in the presence of saliva, as disclosed by Stanley et al.

Claims 10-31, 33-40 and 52-56 are rejected.

Claims 41-51 are withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612